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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,653	08/05/2003	Jan Carlsson	1614-0261P	5460
7590 Holly D. Kozlowski Dinsmore & Shohl LLP 255 E. 5th Street 1900 Chemed Center Cincinnati, OH 45202			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/26/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/633,653

Applicant(s)

CARLSSON ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 9/20/2006 has been received. Claim 1 has been canceled.

Claims 2-17 have been added and are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claims 2-17 are directed to a test kit comprising a flow matrix having a separation zone containing a ligand for which the "binding capacity" for the analyte is to be determined.

This flow matrix is not supported by the specification as originally filed. No where in the specification is there a discussion of such a matrix.

Applicant asserts that the specification at page 15, lines 4-11 provides support for a matrix where the separation zone contains a ligand *for which the binding capacity for the* analyte is to be determined. However, a review of the specification at the cited location,

as well as the entire specification, does not provide adequate support for this limitation. The specification at page 15 discusses the different types of analytes that may be determined and lines 4-11 specifically discusses the binding *capability* of an analyte to a ligand immobilized in the separation zone. Nothing here provides support for determining the *binding capacity* of a ligand for an analyte.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because the preamble of the claim recites that the test kit is used for determining the *binding capability* of a ligand to an analyte; however, the separation zone is recited as containing a ligand for which the *binding capacity* for the analyte is to be determined. Therefore, this claim lacks correlation. Furthermore, the "optional" limitation is indefinite and has not been given patentable weight.

Claim 5 is vague because it is unclear exactly what "conditions" makes the ligand exhibits positive *and* negative charges at the same time.

Claims 11 and 17 are confusing because it is unclear what "library members of a library of compounds" is used. The recitation of "a library of compounds" is also confusing because it is unclear what these compounds are.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 2-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitzpatrick et al (US 5,451,504).

Fitzpatrick discloses a device comprising an application zone, a mobilization zone, a trap zone, a detection zone and an absorbent zone. See figure 1. The mobilization zone comprises labeled receptor for the analyte; the trap zone comprising immobilized ligand that will bind either free receptor or excess analyte. The detection zone comprises immobilized capture reagent for the analyte-labeled receptor complex. See column 4, lines 50-58; column 6, lines 38-44; column 7, lines 15-24, and column 8, lines 13-41. Fitzpatrick is seen to anticipate the claimed test kit because the test kit has nothing more than a device that is taught by Fitzpatrick.

Because the ligand of Fitzpatrick is the same with those of instant claims, i.e. antibodies, therefore, they are expected to exhibit the same characteristics, even though Fitzpatrick does not specifically state that their ligand exhibits a positive and/or negative charge,

Fitzpatrick also does not state that the ligand comprises one or more library members, however, since it is unclear what type of library and compounds is being claimed, the various ligands disclosed by Fitzpatrick can clearly be considered members of a library of compounds.

Response to Arguments

8. Applicant asserts that Fitzpatrick does not teach a flow matrix having a detection zone containing a biospecific affinity capturer reactant firmly anchored therein and a separation zone containing a ligand for which the binding capacity for the analyte is to be determined.

This is not persuasive. Fitzpatrick clearly teaches a detection zone comprising an immobilized binding partner of the receptor. This binding partner binds receptor bound to the analyte, therefore it meets the limitation that the biospecific affinity capturer is *directed* toward an *analyte-related reactant*. There is nothing in the claim that requires the capturer to bind directly to the analyte.

Conclusion

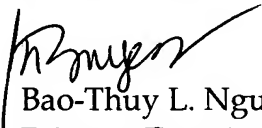
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 12/7/06